

Remarks

Claims 1-40 are pending in this application. Claims 1-40 stand rejected. Claims 1 and 14 are amended herein. Applicants have amended claims 1 and 14 to clarify that all of the concentrations specified in the claims are measured in weight/volume, as taught on page 7, lines 20-26, of the specification. No new matter is presented by way of these amendments to the claims. Support for the amendments to claim 1 can be found, *e.g.*, on page 7, lines 20-21. Support for new claim 41 can be found, *e.g.*, on page 7, lines 23-26.

Provisional Obviousness-type double patenting

Claims 23-33 and 36-39 stand rejected on the grounds of obviousness-type double patenting as allegedly being unpatentable over claims 1-3, 6, 14, 15-18 and 20 of copending US Patent Application No. 10/533,464. US Patent Application 10/533,464 is the National Phase of PCT PCT/EP03/12160, filed 30 October 2003. As of the present date, no claims of US Patent Application No. 10/533,464 have been found to be allowable, thus, this is a provisional obviousness-type double patenting rejection. Since, neither of these applications is currently otherwise in condition for allowance, Applicants respectfully request that the double-patenting rejection be held in abeyance until all other substantive issues of patentability in this application have been resolved.

Claims 1-40 are enabled as required under 35 U.S.C. § 112, first paragraph

Claims 1-40 stand newly rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly “does not reasonably provide enablement for any/all concentrations of stabilizing agent less than 3.5% weight/volume.” To the extent that the Examiner maintains this rejection with respect to the amended claims, Applicants traverse.

35 U.S.C. § 112 requires that “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, is such full clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...” The Court of Appeals for the Federal Circuit has interpreted § 112 to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). However, as indicated in MPEP § 2164.01, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at

737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

Claim 1 is directed to a method for preserving an active agent comprising the steps of:

- a) preparing a preservation sample by dissolving or suspending active agent in a solution of a stabilizing agent comprising a polyol at a concentration of between 1% and 50% (w/v);
- b) subjecting the preservation sample to temperature and pressure conditions such that the preservation sample loses solvent by evaporation without freezing or bubbling, thereby forming a viscous liquid, wherein the active agent retains at least 40% of the antigenicity, activity, immunogenicity, or combination thereof, as compared to a reference sample that has not been subject to the evaporation process.

The Examiner contends that:

The amount of direction or guidance present in the instant specification is insufficient for the broad scope of the instant claims. The specification examples utilized stabilizing concentration of 3.25% to 10% weight/volume.

The quantity of experimentation necessary utilizing $\leq 3.15\%$ determined by other than weight/volume constitutes merely an invitation to experiment without a reasonable expectation of success.

The Examiner appears to base the rejection on the observation that the Examples provided in the specification have utilized stabilizing agents at concentrations within the range of 3.25%-10% weight/volume. However, the specification clearly indicates that lower concentrations are also suitable, and indicates specific (e.g., salt concentration) parameters for choosing between various initial concentrations of stabilizing agent. For example, page 7, lines 20-26 teaches that at lower salt concentrations 2%-10% of stabilizing agent is preferred whereas at higher salt concentration 10%-25% is better.

The Examiner suggests that there would not be a reasonable expectation of success at low levels of stabilizing agent. However, the Examiner points to no teaching either within the instant specification, or otherwise, that casts any doubts whatsoever on the clear teaching that concentrations as low as 1% (w/v) are appropriate in the context of the method of claim 1. Even if such doubts might be warranted with respect to vanishingly small amounts of sucrose, no such doubts can reasonably be raised with respect to the taught and claimed concentrations of at least a 1% solution, because even a 1% solution of stabilizing agent is disclosed in the specification to be a sufficient concentration at the beginning of the evaporation process to protect the active agent during drying and subsequent storage. Thus, given the teaching in the specification, which clearly sets forth an acceptable range, coupled with a demonstration that examples within the specified

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range provide the desired results, the skilled practitioner would readily, and without undue experimentation be able to practice the full scope of the claimed method, with the expectation that so doing would achieve the desired result. Accordingly, the full-scope of claim 1 as amended (and claims dependent therefrom) is enabled by the specification as required by 35 U.S.C. § 112, first paragraph, and the rejection should be withdrawn.

Conclusion

On the basis of the amendments and remarks above, Applicant believes that the claims are now in condition for allowance. In the event that any substantive issues remain, Applicant hereby requests a telephonic interview with the Examiner prior to preparation of any additional written action. Accordingly, the Examiner is invited to contact the undersigned to arrange for an Examiner's interview, or to discuss the status of this application.

Respectfully submitted,



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